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Streamlining Procedures for Single Patient Expanded Access Requests Involving Investigational New Drugs

(Updated October 3, 2017)

Four Steps:

1. Revise IRB application procedures so that the treating physician may submit as the application:

    - FDA Form 3926
    - Investigator brochure or another source describing risks and potential benefits of the treatment
    - Draft consent document

2. Revise procedures to ensure that your IRB is able to handle requests in a timely fashion.

    - As of October 3, 2017, FDA permits the IRB chair or designee to review and concur with the expanded access request.

3. Provide recommendations or similar guidance to your IRB members about how to review single patient expanded access requests.

    - Confirm the medical evaluation of the patient's condition based on the information provided by the treating physician. This individual must be able to confirm or deny the claim that there is no comparable or satisfactory alternative available.
    - Ensure that informed consent or appropriate permissions will be obtained and documented. Given the compassionate nature of the request and FDA's involvement, consent documents should meet the requirements listed in 21 CFR 50.25, using plain language that is specifically aimed at "patients" who expect direct benefit, as opposed to "subjects" who may not expect benefit.
    - Receive documentation that FDA has made its determinations regarding safety and effectiveness and has given clearance for the use. Request the IND number and any documentation from FDA.
    - Review the physician's treatment plan (or sponsor-provided treatment protocol) and determine that it makes adequate provision for ensuring the safety of the patient including adequate monitoring (timing and type of tests/exams, etc.) and appropriate plans for collecting and reporting the data.

4. Publish procedures so that they are available to treating physicians and IRB members.